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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,847	04/10/2006	Jae Yong Han	50413/013001	2565
21559	7590	06/11/2008		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER SAJJADI, FEREDOUN GHOTB	
			ART UNIT 1633	PAPER NUMBER
			NOTIFICATION DATE 06/11/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary

Application No.

10/569,847

Applicant(s)

HAN ET AL.

Examiner

FEREYDOUN G. SAJJADI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CD/CD)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Status

Applicants' response of February 29, 2008, to the non-final action dated August 30, 2007 has been entered. Claims 1-19 are pending in the application. No claims were amended, cancelled or newly added. Claims 16-19 stand withdrawn from further consideration without traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Claims 1-15 are under current examination.

Response to Objections to the Specification/Abstract

The abstract of the disclosure was previously objected to in the office action dated August 30, 2007. In view of Applicants' submission of a new abstract on a separate sheet, in accordance with 37 CFR 1.52(b)(4), the previous objection is hereby withdrawn.

Response to Claim Rejections - 35 USC § 102

Claims 1, 2, 4-10, 12, 13 and 14 stand rejected under 35 U.S.C. 102(e) as being anticipated by Baguisi et al. (U.S. Patent Publication No.: 2002/0162134 effective filing date: Feb. 16, 2001). The rejection set forth on pp. 3-4 of the previous office action dated August 30, 2007 is maintained for claims 1, 2, 4-10, 12, 13 and 14 for reasons of record.

Applicants traverse the rejection, arguing that there are crucial differences between the PGCs and SSCs in view of their isolation sources and morphology; that PGCs are derived from embryonic gonad, which is composed of undifferentiated types of cells, whereas SSCs are derived from testis of adult chicken, which comprises totally differentiated cell types. Further arguing that in the Baguisi reference, PGCs are obtained from gonad of chick embryos incubated for at least 6.5 days whereas the SSCs of the present invention are prepared from testicular cells of testis of the adult chicken of aged

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of up to 70 weeks. Applicants additionally argue that PGCs have many vacuoles in the cytoplasm and well-developed pseudopodia, and in some cases, PGCs also have many lipid drops in the cytoplasm for energy source for migrations or active movements; that SSCs are tighter and smaller than PGCs; that PGCs are more slowly growing *in vitro* or *in vivo* (2-3 days per doubling), however, SSCs are growing faster (less 2 days) than PGCs. Applicants' arguments have been fully considered, but are not found persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., morphological differences, source of tissue and growth characteristics) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The instant claims are directed to a method (not a product), said method comprising the steps of preparing a chicken testis and isolating and culturing a population of spermatogonial stem cells therefrom. The claims do not require the testis to be of any particular stage of development. The instant specification states: "Spermatogonial cells of avians originate from primordial germ cells (PGCs) that ...finally differentiated into spermatogonia in testis." (lines 19-26, p. 1). The instant specification further teaches that like PGCs, SSCs stain purplish red with PAS staining, that makes it possible to discriminate chicken SSCs from Sertoli cells and other cells (lines 13-20, p. 35). Thus SSCs represent an intermediate stem cell that differentiates into spermatogonia. Baguisi et al. teach isolated avian gonadal cells from the testes (Title and Abstract), and methods of isolating and culturing the same. The differentiation of PGCs and SSCs into spermatogonia was known in the prior art and thus their culture must necessarily also comprise any intermediates in the differentiation process.

In response to Applicants' arguments that there is no description of actually obtaining gonad cell from testis in Baguisi, Applicants are directed to paragraphs [0049-0050], pp. 5-6, describing the isolation and culture of the germ cells.

Therefore the rejection is maintained for reasons of record, and the commentary above.

Response to Claim Rejections - 35 USC § 103

Claims 1, 3, 11 and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Baguisi et al. (U.S. Patent Publication No.: 2002/0162134 effective filing date: Feb. 16, 2001), in view of Shinohara et al. (U.S. Patent Publication No: 2006/0265774; effective filing date April 15, 2003). The rejection set forth on pp. 4-5 of the previous office action dated August 30, 2007 is maintained for claims 1, 3, 11 and 15 for reasons of record.

Applicants traverse the rejection, arguing that the instant method relates to the culture of chicken spermatogonial stem cells prepared from the testis of adult chicken, whereas the Baguisi reference discloses the isolation of primordial germ cells from embryonic gonad cell. Applicants' arguments have been fully considered, but are not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Baguisi et al. describe isolated avian gonadal cells from the testes (Title and Abstract), and methods of isolating and culturing the same. Applicants are directed to the response provided above regarding the teachings of the instant method steps by Baguisi et al.

Applicants further argue that the Shinohara reference, discloses a method of growing spermatogonial stem cell (SSCs) from the mammalian testis, especially mouse, and does not teach the culturing method of the SSCs from chicken testis, arguing differences between mouse SSCs and chicken SSCs in morphology and shape of colony.

In response, it is again noted that there is no requirement that a single reference teach each and every limitation of a claim in an obviousness rejection based on the combined teachings of two references. Shinohara et al. describe a method for growing spermatogonial stem cells isolated from testis, *in vitro*. It would have been *prima facie* obvious for a person of ordinary skill in the art to combine the teachings of Baguisi et al.

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and Shinohara et al. (as both describe methods for the preparation and culture of sperm stem cells), to isolate sperm stem cells from an avian testis.

Therefore the rejection is maintained for reasons of record, and the foregoing remarks.

Conclusion

Claims 1-15 are not allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fereydoun G. Sajjadi, Ph.D.

Examiner, Art Unit 1633

/Anne Marie S. Wehbe/

Primary Examiner, Art Unit 1633